K003723

MAR 2 7 2001

510(k) Summary

1. **Name of Manufacturer**

Minnesota Mining and Manufacturing (a.k.a. 3M)
Medical-Surgical Division
3M Center
St. Paul, MN 55144-1000

2. **Regulatory Correspondent of Device Manufacturer:**

Linda Johnsen
Regulatory Affairs Specialist
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000
651 737- 4376

3. **Date Summary was prepared:** December 1, 2000

4. **Regulatory Information:**

Device Name: Electronic, Stethoscope
Proprietary Name: 3M™ Littmann™ Electronic Stethoscope, Model 4000
Common Name: Electronic Stethoscope
Class: II
PRO Code: DQD (870.1875)
FDA Mandatory Performance Standards: None

5. **Predicate Device to which 3M is claiming Substantial Equivalence:**

3M™ Littmann™ Electronic Stethoscope, Model 2000 cleared for market under Premarket Notification k961848

6. **Device Description of New Device Subject to Premarket Notification**

The 3M™ Littmann™ Electronic Stethoscope, Model 4000 provides three filter frequency modes for auscultation: Bell (20-200Hz), Diaphragm (100-500Hz) and Extended Range (20-1000Hz). This stethoscope provides amplification and includes features that permit it to record and store sounds on each of its six soundtracks. The recordings of the heart, lung and other body sounds can be up to eight seconds in length

on each soundtrack. The Model 4000 can playback the recordings at normal and half speed.

The Model 4000 has an infrared data transmission port which permits the recorded sounds to be transferred to another Model 4000 or an IBM-compatible PC that has an Infrared Port and Windows 95/98/00.

The Model 4000 includes a LCD display on the chestpiece that displays the heart rate, volume level, track number, record and playback, playback speed, filter frequency mode and low-battery indicator.

The Model 4000 incorporates embedded software. The embedded software controls all of the various features found in the Model 4000 stethoscope such as the volume control, frequency mode selection, LCD display, record and playback, and the infrared data transfer. In addition, the embedded software also provides digital signal processing (DSP). The digital signal processing produces the bell, diaphragm, and extended frequency response modes that are used to listen to heart, lung, and other body sounds. The Model 4000 does not incorporate any off-the-shelf (OTS) software.

The Model 4000 operates on two (2) AAA alkaline batteries.

7. Indications for Use of New Device Subject to Premarket Notification:

The 3M™ Littmann™ Electronic Stethoscope Model 4000 is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

8. Comparison Data of Predicate Device to New Device:

The following Table 1 illustrates the similarities and differences of the predicate device (Model 2000) compare to the new device (Model 4000). The 3M™ Littmann™ Electronic Stethoscope, Model 4000 is substantially equivalent to the 3M™ Littmann™ Electronic Stethoscope, Model 2000.

Table 1
Similarities and Differences of the Predicate Device (Model 2000)
Compared to the New Device (Model 4000)

Characteristics	**Predicate Device 3M Littmann Electronic Stethoscope, Model 2000**	**New Device Model 4000**
Performance Features		
Frequency Response Mode	Bell (20-200Hz), Diaphragm (100-500Hz) and Extended Range (500-1000Hz)	Bell (20-200Hz), Diaphragm (100-500Hz) and Extended Range (20-1000Hz)
Amplification	Up to 25dB acoustic gain, equivalent to 18 times amplification	Up to 20dB acoustic gain, equivalent to 14 times amplification
Maximum Sound Level	140dB SPL Max	140dB SPL Max
Displays Heart Rate	Yes	None
Permits Data Transfer of Stored Digital Signal to and from IBM-Compatible PC*:	Yes	None
Volume Control	8 Step Volume Control	Continuous Variable
Energy Source	Two (2) AAA alkaline batteries	One (1) AAA alkaline battery
Manual On/Off Button Automatic Shut-Off by Electronics	Yes	Yes
Embedded Software	Yes (Digital Signal Processing)	None (Analog)
Low Battery Indicator	Yes	Yes

*** With Infrared Port and Windows™ 95/98/00**
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Ms. Linda Johnsen
Regulatory Affairs Specialist
3M Medical-Surgical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

Re: K003723
Trade/Device Name: 3M™ Littmann™ Electronic Stethoscope, Model 4000
Regulatory Class: II (two)
Product Code: 74 DQD
Dated: March 16, 2001
Received: March 20, 2001

Dear Ms. Johnsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): _____

Device Name: 3M™ Littmann™ Electronic Stethoscope, Model 4000

Indications for Use:

The 3M™ Littmann™ Electronic Stethoscope Model 4000 is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003723

Prescription Use X OR Over-the Counter Use _____

(Optional Format 1-2-96)